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Award Number: W81XWH-07-1-0311

TITLE: Crozer-Chester Medical Center Burn Research Project

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CONTRACTING ORGANIZATION: Crozer-Chester Medical Center
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REPORT DATE: July 2011

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
July 2011	Annual	19 June 2010 – 18 June 2011

4. TITLE AND SUBTITLE

Crozer-Chester Medical Center Burn Research Project

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-07-1-0311

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Crozer-Chester Medical Center
Upland, PA 19013-3995

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The purpose of the research is to conduct burn research that will benefit combat casualties in the current conflict. The Nathan Speare Regional Burn Treatment Center is under contract with the U.S. Army Institute for Surgical Research and the Army Burn Center to carry out two studies according to protocols established by Army researchers. The purpose of Study 1, Automated Fluid Resuscitation of Burn Patients, is to collect data which will be used to create an effective resuscitation algorithm for the development of a closed loop resuscitation system. Approximately 20 patients will be enrolled in the Crozer Burn Treatment Center. Study 2, Evaluation of Aquacel Ag, will compare the performance of Aquacel Ag to the normal standard of care (Xeroform). Approximately 20 patients will be enrolled. A third study, A Comparison of Clinical and Microbiological Efficacy of Three Separate Antibiotic Regimens Against Acinetobacter baumannii, has been designed by the Principal Investigator and will be carried out at Crozer only. During the year, Crozer and the Army installed 2 computers/software to permit data collection for Study 1 (April, 2011) and began enrolling patients. Two patients were enrolled during this report period. Study 2 is continuing enrollment, with 14 patients completing the study to date. Study 3 had no patients that met criteria for enrollment, due to the elimination of the drug resistant organism. A new study has been identified and discussed in the report.

15. SUBJECT TERMS
Automated fluid resuscitation devices, Closed-Loop algorithms, Kramer resuscitation; Aquacel Ag Dressing, Donor site care; Acinetobacter baumannii;

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	16	19b. TELEPHONE NUMBER *(include area code)*

Crozer-Chester Medical Center Nathan Speare Regional Burn Treatment Center

Annual Report Year 4
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Crozer-Chester Medical Center Nathan Speare Regional Burn Treatment Center

ANNUAL REPORT TO THE U.S. ARMY INSTITUTE OF SURGICAL RESEARCH FOR THE PERIOD 6/19/2010 to 6/18/2011 (Year 4)

Title: "Crozer-Chester Medical Center Burn Research Projects"

Contract Number: W81XWH-07-1-0311, as amended

INTRODUCTION:

The purpose of the proposed project is to conduct burn research that will benefit combat casualties in the current conflict. The Army Burn Center, which is part of the Brooke Army Medical Center in Fort Sam Houston, Texas, has demonstrated the applicability of burn research in civilian populations to combat populations. The Nathan Speare Regional Burn Treatment Center is under contract with the U. S. Army Institute for Surgical Research to carry out two projects according to protocols that have been already established by Army researchers. A third project has been defined by Crozer's Principal Investigator. These projects are:

Study 1: "Automated Fluid Resuscitation of Burn Patients"
The purpose of Study 1 is to collect data which will be used to create an effective resuscitation algorithm for the development of a closed loop resuscitation system. The actual use of the closed loop resuscitation system will occur in a future study. Approximately 20 patients will be enrolled. The projects are expected to improve resuscitation of burn patients by creating a feedback loop of actual patient response to resuscitation volumes, and titrating the fluid therapy to changes in urinary output. Data from urometers, cardiac monitors and IV pumps will be measured at 10-minute intervals and fed to a DAQ, which is a computer system designed to collect data from this equipment at the bedside.

Study 2: "Evaluation of Aquacel Ag Dressing for Autogenous Skin Donor Sites"
This study will compare the performance of an agreed upon dressing to the normal standard of care (Xeroform). Patients who are scheduled for excision of burns or other injuries will have one of two donor sites covered with the Aquacel Ag dressing, and the other treated according to standard care. Approximately 30 patients will be enrolled. The hypothesis is that mean healing time for wounds treated with Aquacel Ag dressing will be less than the mean healing time for wounds treated with Xeroform dressing. Specific aims are: 1) that pain as perceived by the patient will be equal to or less than with the Aquacel Ag dressing as compared with the standard dressing, and 2) the cosmetic effect of healing at post surgery day 30-45 will be equal or less with the Aquacel Ag dressing as compared with the standard of care dressing.

Study 3: A Comparison of Clinical and Microbiological Efficacy of Three Separate Antibiotic Regimens Against *Acinetobacter baumanni*.
A. baumannii has been steadily emerging as a poly-resistant organism in burn treatment centers. In addition to the problem of widespread colonization of patient care areas, there has been the progressive development of multiple resistance genes. The goal of this project is to evaluate the microbiological and clinical efficacy of three potential antimicrobial agents over 24-months in

three groups of 20 adult patients with documented *A. baumannii* infections to determine if there are any subtle or frank differences in outcome with the use of these antimicrobials. Using standard manufacturer-recommended doses, we intend to compare two agents that have not been routinely used, colistin and tigacycline, to imipenem-cilistatin to guide best practices in *A. baumannii* treatment. Using standard statistical testing methods the duration of treatment, time to onset of infection, and other parameters will be investigated. Standard assessment of infection response will be used to evaluate and compare these three agents. Pilot data on Crozer burn patients with *A. baumannii* pneumonia will also be analyzed.

BODY:

The approved Statement of Work is as follows:

Study 1, Protocol Title: "Automated Fluid Resuscitation of Burn Patients – Phase 1"

Task 1: To collect data from 20 study subjects which will be used to create an effective resuscitation algorithm for the development of a closed loop resuscitation system.

a. Complete project start-up activities (hiring and training of research staff, purchasing equipment) (Year 1, Quarter 1)
b. Enroll 15 study subjects and collect data (Year 1, Quarters 2-4)
c. Enroll 5 study subjects and collect data (Year 2, Quarter 1)

Study 2, Protocol Title: "Evaluation of Xxx for Autogenous Skin Donor Sites"

Task 1: Enroll up to 30 patients in this multi-center trial to evaluate the performance of the identified dressing versus standard of care dressing (Xeroform) for skin donor sites in terms of day of healing, comfort, cosmetics and ease of use.

a. Complete project start-up activities (hiring and training of research staff) (Year 1, Quarter 1)
b. Enroll 75% of study subjects, harvest subject's donor sites, randomize dressing to donor sites, and conduct clinical assessments (Year 1, Quarter 2-4)
c. Enroll 25% of study subjects, harvest subject's donor sites, randomize dressing to donor sites, and conduct clinical assessments (Year 2, Quarter 1)
d. Summarize results (Year 2, Quarter 1)

Study 3, Protocol Title: "A Comparison of Clinical and Microbiological Efficacy of Three Antibiotic Regimens Against *Acinetobacter baumannii*"

Task 1: To collect data from three groups of 40 patients and to compare the responses to antibiotic therapy with specific focus on: 1) differences in duration of therapy; 2) differences in time to eradication of infection (laboratory findings changes, vital signs, culture results); 3) differences in adverse reaction profiles of the patients; and 4) impact on the susceptibility of *A. baumannii* to these agents over a two year period.

a. Complete project start-up activities (hiring and training research staff) (year 1, quarter 1)
b. Enroll 45 subjects and collect data (year 1, quarters 2-4)
c. Enroll 15 subjects and collect data (year 2, quarters 1)
d. Enroll 60 additional subjects (year 2, quarters 2-4, Year 3, quarter 1)
e. Compose report, submit abstract for national meeting presentation, write manuscript for publication (year 4, quarter 2)

(Note: 'd' and 'e' will extend beyond the grant period. See Proposal Narrative)

Discussion

Study 1 (Resuscitation Study): During the period of this annual report until the site visit with the USAISR, the burn research team moved forward with educating the entire burn center staff on details of the resuscitation study. This included competencies on Alaris IV pumps, the AbVisor and the Urometer equipment. Crozer engineers coordinated our monitoring equipment in preparation for connection to the DAQ computer. The research nurse continued to remain in on-call status (not billed to the grant). In August, 2010, USAISR notified us that they needed to upgrade the software design prior to the installation site visit. Crozer requested a 2-year contract time extension which was approved. In September and October, the USAISR engineers continued to upgrade the software. Finally, in November, 2010, an engineering site visit occurred. Two laptops were installed instead of one DAQ machine giving us added capacity to enroll patients. However, cables and the updated software were still not available. In December, we continued detailed education of the burn team on the study protocol details. The cables arrived, but not the software. In January, 2011, we began screening patients in anticipation of the software's imminent arrival. The burn research nurse went to full-time status on the grant on 1/31/2011. We continued screening (but not enrolling) patients and as of March 31, a total of 114 patients had been screened (note: only 5 of these 114 patients would have met the study criteria had the software been available). In April, 2011, the software upgrade (patch) was received and the study was able to commence. An additional 34 patients were screened that month. One patient met criteria for the study, however, the computer and software did not function properly requiring intervention by the Army's engineer. Enrollment of this patient was delayed by this work, being enrolled at the 25.5 post injury hour mark (the protocol requires enrollment at 24 hours or less, however we continued data collection on this patient for 48 hours). By the end of April, 2011, both computers were fixed and functional. At the end of the report year (June, 2011), 240 patients had been screened, 2 patients were enrolled. To date, we have screened every admission on a 24/7 basis with on-call coverage of the research team. A summary of patients screened and entering the study is shown in the table below.

AUTOMATED FLUID RESUSCITATION STUDY MONTHLY SUMMARY

JAN 2011-JUN 2011	JAN	FEB	MAR	APR	MAY	JUN	TOTAL	STUDY TOTAL
# SCREENED	43	38	33	34	37	55	240	240
# <20% BSA	40	37	32	33	35	52	229	229
# <18 YEARS OLD	10	7	12	8	9	8	54	54
# NON-BURN	3	4	3	0	6	6	22	22
# >20% BSA	3	1	1	1	2	3	11	11
# INCLUDED IN STUDY	0	0	0	1	0	1	2	2
# EXCLUDED	43	38	33	33	37	54	238	238
DATE LAST UPDATED	1/31/2011	2/28/2011	3/31/2011	4/30/2011	5/31/2011	6/30/2011		
		1		2	3	4		

1) Computer set-up was not complete so we could not enroll any patients. 2) Computer issues resulted in starting pt on DAQ at approx 25.5 hrs after burn injury. Data still collected. 3) 1 pt qualified, but initial BSA was less than 20%. 2nd assessment was greater than 20%, but Pt not being resus, no central line. 2nd pt qualified, but family not available in person to obtain consent. 4) 1 pt qualified, no research staff available when pt admitted. 2nd pt had myoglobin in urine, unknown med hx, and no family.

The strict exclusion criteria for Study 1 which, among other exclusions, includes a requirement that the patient to be enrolled within 24 hours of injury, combined with the Crozer IRB requirement of obtaining informed consent directly from family members of the patient, have proven to be problematic to the study. In addition, with the trend to decrease the incidence of hospital acquired infections related to central lines, the use of peripheral IV lines for certain patients has become standard of care. This has put another barrier into meeting enrollment criteria for this study (which requires central lines and foley catheters). Several patients have also refused foley catheters. The study stipulates that the standard of care cannot be changed. We are making every effort to address these barriers in the coming year. However, we anticipate that due to the delays in start-up that were outside our control, we will have a need for a contract extension when it expires in July, 2012.

Study 2 (Donor Site Study): Enrollment of patients into this study began in April, 2009 and continued throughout this study year. A total of 480 patients were screened during this contract period (July, 2010 to June, 2011). During this time period, 8 patients were enrolled, bringing the total enrollment at the end of the period to 17. The Research Nurse makes daily rounds on the burn unit to identify possible candidates for the study. Due to the limits of the eligibility criteria, enrollment has been difficult. However, despite this, we anticipate no problems in achieving the study objectives in the coming year. A full internal audit of all data collected to date was completed. Several of the screening numbers have changed as a result of this audit. A summary of patients screened and entering the study is shown in the table below.

Research Monthly Summary
FY2009-2010
Donor Site Study-AquaCel AG

AQUACEL AG DONOR STUDY MONTHLY SUMMARY														
MAR 09-JUN 09	**JUL**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**TOTAL**	**STUDY TOTAL**
# PATIENTS SCREENED									21	45	38	37	141	141
									3/15-3/31					
# MEETING CRITERIA									1	1	1	1	4	4
# EXCLUDED									20	44	38	37	139	139
# ENROLLED IN STUDY									1	1	0	0	2	2
# COMPLETING STUDY									1	1	0	0	2	2
# DECLINED												1	1	1

Research Monthly Summary
FY2009-2010
Donor Site Study-AquaCel AG

AQUACEL AG DONOR STUDY MONTHLY SUMMARY														
JUL 09-JUN 10	**JUL**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**TOTAL**	**STUDY TOTAL**
# PATIENTS SCREENED	58	34	25	46	34	33	34	31	37	50	39	49	470	611
# MEETING CRITERIA	1	1	2	0	0	0	2	2	3	0	0	0	11	15
# EXCLUDED	57	33	25	46	34	33	32	29	36	50	39	49	463	602
# ENROLLED IN STUDY	1	1	0	0	0	0	2	2	1	0	0	0	7	9
# COMPLETING STUDY	1	1	0	0	0	0	2	2	1	0	0	0	7	9
# DECLINED	0	0	0	0	0	0	0	0	2	0	0	0	2	3

Research Monthly Summary
FY2010-2011
Donor Site Study-AquaCel AG

AQUACEL AG DONOR STUDY MONTHLY SUMMARY														
JUL 10-JUN 11	**JUL**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**TOTAL**	**STUDY TOTAL**
# PATIENTS SCREENED	46	34	43	32	46	39	43	38	33	34	37	55	480	1091
# MEETING CRITERIA	2	0	3	4	2	7	3	0	2	0	2	1	26	41
# EXCLUDED	44	34	43	28	46	38	43	38	31	34	35	54	468	1070
# ENROLLED IN STUDY	1	0	0	1	0	1	0	0	2	0	2	1	8	17
# COMPLETING STUDY	1	0	0	0	0	1	0	0	1	0	2	0	5	14
# DECLINED	1	0	1	3	0	4	3	0	0	0	0	0	12	15
# PTS <18 YEARS OLD							10	7	12	8	9	8	54	54
# NON-BURN PTS							3	4	3	0	6	6	22	22
DATE LAST UPDATED							1/31/11	2/28/11	3/31/11	4/30/11	5/31/11	6/30/11		
Notes Number									1		2	3		

Notes:
1) 1 pt removed from study due to non-compliance. 2) 1 pt with road rash excluded. 3) 1 pt agreed, but only if donors on 1 thigh. Saw in OR. Would have had to do 2 thighs to be in study.

Research Monthly Summary
FY2011-2012
Donor Site Study-AquaCel AG

AQUACEL AG DONOR STUDY MONTHLY SUMMARY														
JUL 11-JUN 12	**JUL**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**	**JAN**	**FEB**	**MAR**	**APR**	**MAY**	**JUN**	**TOTAL**	**STUDY TOTAL**
# PATIENTS SCREENED	52	57	33	32	26	5							205	1296
# MEETING CRITERIA	3	0	3	1	0	1							8	49
# EXCLUDED	49	57	31	31	26	5							199	1269
# ENROLLED IN STUDY	3	0	2	1	0	1							7	24
# COMPLETING STUDY	3	0	0	1	0	0							4	18
# DECLINED	0	0	1	0	0	0							1	16
# PTS <18 YEARS OLD	13	16	7	6	4	0							46	100
# NON-BURN PTS	4	2	4	3	3	0							16	38
DATE LAST UPDATED	7/31/2011	8/31/2011	9/30/2011	10/31/2011	11/29/2011	12/5/2011								
Notes Number	1	2	3											

Notes:
1) 3 pts currently enrolled and are expected to complete study in next 1-2 weeks. 2) 2 pts with extensive psych hx excluded. 2 pt w/ road rash excluded. 1 pt missed. Was not aware pt was going to OR. 3) 2 pts enrolled. 1 removed from study on POD #6 due issues w/ Aquacell site. Pt was followed until healed in outpt clinic. 1 pt was no call, no show for 3 outpt appts. Unable to obtain photos 30-45 days post-op.

Study 3: Study 3, a project defined by Crozer, has not begun because Crozer has not had any patients that met the criteria for inclusion since April, 2008. The study was focused on the poly-resistent A. Baumanii, which was eliminated in the burn unit in 2007 and has not recurred. In order to fully utilize the burn research nurse, we have worked on other projects applicable to the military theatre which have contributed to other areas of burn research. In the report period from July to January, 2011, we completed a project on the effects of low hemoglobin on bedside point of care glucose monitoring. These projects are summarized below.

Presented at 2011 ABA

- Evaluation of the Relationship Between Elevated Vancomycin Trough Concentrations and Increased Efficacy and/or Toxicity
- Burn Center Management of Operating Room Fires
- Use of nebulized antimicrobial agents in thermal injury patients due to persistence of Acinetobacter baumannii, Pseudomonas aeruginosa, or Enterobacteriacea in ventilated patients

Presented at 2011 SIS (Surgical Infection Society)

- APRV as a Rescue Mode in Inhalation-Induced ARDS

Accepted for 2012 ABA

- Management of Purpura Fulminans in a Burn Treatment Center
- Pyoderma Gangrenosum in a Burn Treatment Center
- Trimethoprim-induced hyperkalemia in burn admissions treated with intravenous or oral trimethoprim sulfamethoxazole
- Impact of multiple drug resistant (MDR) Acinetobacter baumannii on changes in antibiotic susceptibility of Pseudomonas aeruginosa

Accepted for 2012 SCCM (Society of Critical Care Medicine)

- Point of Care Glucose Monitoring May Be Unreliable in Critically Ill Burn Patients with Low Hemoglobin

Submitted to SIS for 2012 (Surgical Infection Society)- awaiting acceptance

- Relationship Between Nasal Swab Methicillin-Resistant Staphylococcus Aureus (MRSA) PCR-Positive Rest Results and Subsequent MRSA Infection in Thermal Injury

The narrative below summarizes the project activities for Study 1 and Study 2 for each month of the project year, as documented in the project's quarterly reports:

July 2010

Study #2 – Donor Site Study continues. Patient #10 has been completed. We are preparing for our first transmission of data to the primary PI at the USAISR. The Burn Research Nurse completes daily rounds to identify patients for the donor site study. Weekly Research Meetings continue with the team to ensure IRB dates remain active and current.

Study #1 – Resuscitation Study Status: Clinical equipment has been purchased and delivered. The DAQ machine is now a laptop computer and we are in the procurement process of two additional laptops to covert to a DAQ computer. Two dates for site visits had been arranged; June 2, 2010 and July 1, 2010. Both visits were cancelled at the last minute by the USAISR representatives due to sudden issues arising preventing travel. We are currently awaiting USAISR response with a new date. We have proposed September 15, 2010 as a suggested date for site visit. In the meantime all burn center staff are in the process of being educated on the Alaris IV pumps, AbVisor and Urometer equipment in preparation for the site visit. Crozer engineers are ready to meet the USAISR team to coordinate our monitoring equipment to the DAQ computer. We anticipate our first patient to be enrolled after this visit has occurred. Once the visit has been successful, the research nurses will begin their full time status in an on-call position until we enroll our first patient.

August 2010

Study #2: No patients were enrolled this month. The total number of patients enrolled remains 10.

Study #1: We are still awaiting the USAISR site visit. The delay occurred due to the need to upgrade the software design prior to installation at our site. The grant was awarded a two year extension to allow for the Resuscitation Project to commence. All equipment is ready to go at this site.

September, 2010

Study #2: Donor Site Study continues. The past month there has been one eligible enrollee who declined. This keeps the total at 10 completed patients in the study.

Study #1: We received contact from Dr Wolf on September 14th that the team was ready to move forward. The engineers were finalizing the software. An October visit is being planned. All equipment is ready to go at this site.

October, 2010

Study # 2: Donor Site Study continues. The past month there have been four eligible enrollees, 3 of whom declined to participate. One patient enrolled in the study, bringing the total enrollment number to 11.

Study # 1: We are still awaiting the site visit from the Army. Dr Haith is preparing the education of the staff.

November, 2010

Study # 2: Donor Site Study continues. 46 patients were screened this month; 2 patients met criteria however both were excluded based on inability to be compliant with care after discharge.

Study # 1: The Army Engineer site visit occurred this month. Intensive education of the burn team began with the study details and the equipment. Both Research Nurses participated in the education of the staff. The Crozer IS representative and the Clinical Engineers were present at the meeting as well. All computers and cardiac monitoring systems were meshed. We were missing small details of cables and still need the updated software that will soon be released to us when it is ready.

December, 2010

Study # 2: Donor Site Study continues. One patient enrolled in the study bringing the total enrollment number to 12. We continue to screen all admissions for study inclusion.
Study # 1: Cables have arrived. The software update is still not available to us. We continue with education of the team.

January, 2011
Study # 2: Donor Site Study continues. 43 patients were screened; 3 met criteria; 3 declined and no patients were enrolled into the study. The total number of patients enrolled remains 12.
Study # 1: We have completed all training of the burn team in preparation to begin the Resuscitation Study. All equipment has been in-serviced and is ready to go. We still await the patch for the software program for the DAC Computer from the Army Engineer. We anticipate this coming any day. We have begun screening patients in January. 42 patients screened; 3 patients met the criteria by % TBSA. However, due to the computer issues, we were not able to begin study enrollment.

February, 2011
Study #2: Donor Site Study continues. 38 patients were screened; 0 met criteria. Total of 12 enrolled patients.
Study #1: Resuscitation Study Status: We still await the patch for the software program for the DAC Computer from the Army Engineer. We were unable to enroll any patients due to computer issues. 38 patients were screened; 0 patients met the criteria by % TBSA. Total of 80 screened to date.

March, 2011
Study #2: Donor Site Study continues. 33 patients were screened; 2 met criteria; 0 declined; 2 patients were enrolled in to the study and 1 patient completed. The second patient was removed from the study due to non-compliance. Total of 14 enrolled patients. Total of 12 completed the study.
Study #1: Resuscitation Study Status: We still await the patch for the software program for the DAC Computer from the Army Engineer. We were unable to enroll any patients due to computer issues. 33 patients were screened; 1 patient met the criteria by % TBSA. Total of 114 screened to date.

April, 2011
Study #2: Donor Site Study continues. 34 patients were screened; 0 met criteria. Total patients screened to date are 999.
Study #1: Resuscitation Study Status: We received the patch for the software. The computer system is up and running. We are ready to enroll. 34 patients were screened; 1 patient met the criteria by % TBSA; 1 patient enrolled. Due to computer connection, delay in data collection caused patient to be started in system after the 24 hrs mark to enroll. Data collected for 48 hrs and saved despite starting at 25.5 hours post-injury. Total of 147 patients screened to date.

May, 2011
Study #2: Donor Site Study continues. 37 patients were screened; 2 met criteria; 2 patients enrolled; 2 patients completed the study. Total of 16 enrolled patients. Total of 1036 screened patients to date.

Study #1: Resuscitation Study Status: 37 patients were screened; 2 patient met the criteria by % TBSA; 0 patient enrolled. First patient initially <20% TBSA burns; upon second assessment re-calculation within the 24 hrs time frame was >20% TBSA – however patient did not meet criteria of protocol to fluid resuscitate. Patient therefore, did not meet further criteria of study. Second patient arrived with no available family to give consent. Research team is required by our IRB to obtain consent from family in-person. Family never arrived to burn center until past the 24 hr post-injury time frame. Total of 184 patients screened to date.

June, 2011

Study #2: Donor Site Study continues. 55 patients were screened; 1 met criteria; 1 patient enrolled into the study. However, he did not complete the study. He withdrew his consent when he realized that he would have two donor sites on two different legs verses two donor sites on one leg. Patient did not have enough leg space to support two donor sites on one leg. Total of 1 enrolled patients. Total of 1091 screened patients to date.

Study #1: Resuscitation Study Status: 55 patients were screened; 3 patients met the criteria by % TBSA; 1 patient enrolled. First patient lost to enrollment due to unavailability of research staff to enroll patient. Second patient met criteria for %TBSA, however clinical condition excluded patient from study; third patient was enrolled into study and completed entire 48 hrs collection of data. Total of 2 patients enrolled into study and total of 240 patients screened to date.

KEY RESEARCH ACCOMPLISHMENTS:

We have completed about 2/3 of our enrollment target for Study 2 (17/30) and continue to enroll patients. Study 1 commenced enrolling patients in April, 2011.

REPORTABLE OUTCOMES:

For this report year, only 2 patients have completed Study 1. In the next report year, active transmission of data will occur. For Study 2, data will be entered into an Excel spreadsheet and validated. This data will be forwarded to the USAISR when 24 patients have completed the study. The Army will be responsible for statistical analysis of all data and for determining and reporting project outcomes.

CONCLUSION:

Conclusions will be drawn at the completion of the research projects.

REFERENCES:

No publications have been completed.

APPENDICES:

Not applicable.